REMARKS

This application is a broadening reissue application that was filed within two years of the issue date of U.S. Patent No. 6,264,659. Claims 1-11 have been allowed while Claims 12-22 are pending. In the Office Action mailed on March 27, 2008 the Examiner rejected Claims 12-24 under 35 U.S.C. 103(a). Through this amendment, Applicants have amended claims 12-17, 19, 20, and 22 relative to the previous amendment paper. Claims 23 and 24 have been canceled from prosecution without prejudice. Claim 12 has been amended to depend from claim 2 and include the limitation wherein the thermoplastic material is a geometric isomer of natural rubber. Claims 13-17, 19, 20, and 22 have been amended solely to change dependencies from claim 12 to claim 2. No new matter has been entered. All claim amendments, including new claims and amendments to new claims, have been made with markings showing changes relative to the issued patent as required by 37 CFR 1.173(d)&(g). Claims 23 and 24 have been canceled by a statement canceling the claim without presentation of the text of the claim as required by CFR 1.173(b)(2). Applicants respectfully request favorable consideration of the present application in light of the amendments to the claims and the following remarks.

I. Claim Status

Claims 1-22 are now pending. Claims 1, 12-17 and 19-22 have been amended. Original claims 2-11 and 18 remain unchanged. New claims 23 and 24 have been added. The status of the pending claims is as follows.

CLAIM	STATUS
1-22	Pending
23-24	Canceled

II. Explanations for Amendments to Claims

The support in the disclosure of U.S. Patent No. 6,264,659 for the changes made to the claims (*i.e.,* amended claims 1, 12-17 and 19-22 and new claims 23-24) is found in at least the following sections of the '659 patent set forth below under the respective claim(s).

Claim 1 has been amended as follows:

1. A process of replacing nucleus pulposus of an intervertebral disk, comprising:

[identifying a location of a rupture in an annulus fibrosus of an intervertebral disk;]

removing nucleus pulposus associated with [said] an annulus fibrosus of [said] an intervertebral disk; and

injecting a thermoplastic material heated to a temperature over 50 C. for flowing into said annulus fibrosus and then permitting said material to cool for setting in a non-flowing state upon reaching a temperature of between 35 C. and 42C., so as to cause said material to occupy a space formerly occupied by said removed nucleus pulposus.

Line No.	Support For Amendment
8	Figure 3 (nucleus pulposus removed from areas adjacent to the rupture, aperture or hole 14, as well as the interior away from said rupture, aperture or hole 14). Column 1, lines 30-35 (annulus fibrosus may be accessed via tear, puncture, rupture or prolapse). Column 1, lines 43-45 (disk site may be surgically accessed).

Claim 12 has been amended as follows:

12. The injection device as defined in claim [4] 2, wherein the thermoplastic material comprises a geometric isomer of natural rubber.

Line No.	Support For Amendment
1-2	Column 4, lines 33-36 (A thermoplastic material which has been found to be highly satisfactory is gutta percha or a gutta percha compound. Gutta percha is a geometric isomer of natural rubber.).

Claim 13 has been amended as follows:

13. The injection device as defined in claim [4] 2, wherein said [heater] heating element heats said thermoplastic material for flowing at a temperature between about 150C and 200C.

Line No.	Support For Amendment
1-2	Figure 3 (showing a heating element 28 provided to heat the thermoplastic material). Column 4, lines 53-56 (a heater 28 is provided to heat the thermoplastic material).
2-3	Column 5, lines 21-27 (Generally the lowest temperature to which the thermoplastic material is heated while utilizing a large diameter needle such as 1 centimeter in diameter with a relatively high axial force may be 50 C, while the highest temperature will be less than about 250 C. The optimum temperature is about 185 C, within an optimum range between about 150 C and 200 C).

Claim 14 has been amended as follows:

14. The injection device as defined in claim [4] 2, wherein said thermoplastic material comprises a linear crystalline polymer.

Line No.	Support For Amendment
1-2	Column 2, lines 25-30 (A thermoplastic material which has been found to be highly satisfactory is gutta percha which is normally combined with other elements or ingredients in a suitable gutta percha compound. Gutta percha is a linear crystalline polymer which melts at a predetermined temperature, and a random but distinct change in structure results).

Claim 15 has been amended as follows:

15. The injection device as defined in claim [4] 2, wherein said thermoplastic material comprises a gutta percha compound in which gutta percha is between 15% and 40% by weight of the compound.

Line No.	Support For Amendment
1-3	Column 2, lines 25-30 (A thermoplastic material which has been found to be highly satisfactory is gutta percha which is normally combined with other elements or ingredients in a suitable gutta percha compound. Gutta perdha is a linear crystalline polymer which melts at a predetermined temperature, and a random but distinct change in structure results. Column 2, lines 45-52 (A suitable gutta percha compound is dental gutta percha which contains by weight only about 20% gutta percha with zinc oxide comprising about 60% to 75% of the material. The remaining 5% to 10% consists of various resins, waxes, and metal sulfates. The percentages listed are directed to an optimum gutta percha compound. The preferred percentage of gutta percha is in the range of 15% to 40%.)

Claim 16 has been amended as follows:

16. The injection device as defined in claim [4] 2, wherein said injection needle is formed of a ceramic material.

Line No.	Support For Amendment
1-2	Figure 3 (an injection needle 38 preferably formed of silver extends from body 24 and has a ceramic sheath 40 about a portion of needle 38). Column 2, lines 63-66 (The injection device may utilize a silver needle, encased in ceramics, of about 20 to 30 centimeters in length with a diameter as high as 1 centimeter).

Claim 17 has been amended as follows:

17. The injection device as defined in claim [4] 2, further comprising:

an expandable sleeve about said needle adjacent an extending end of said needle to define an annulus between said needle and said sleeve, so that pressurized fluid communicating with the annulus expands said sleeve outwardly.

Line No.	Support For Amendment
1-3	Figure 7 (a detachable balloon dilator sleeve 106 extends about the extending end of needle 104 having lateral openings 107).
4-5	Figure 7 (Piston 108 is effective to pressurize the fluid for flow through openings 107 for expansion of sleeve 106 as shown in broken lines in FIG. 7. Dilator sleeve 106 upon injection of needle 104 in a disk of the spine is expanded for exerting an expanding force against the disk).

Claim 19 has been amended as follows:

19. The injection device as defined in claim [4] 2, further comprising:

a chamber for receiving a plug of said thermoplastic material;

a piston adjacent an end of said plug for exerting a force against said plug; and

a hand operated trigger [is] operatively connected to said piston and upon actuation is effective to force said thermoplastic material from said needle when said thermoplastic material is heated to a flowing state.

Line No.	Support For Amendment
1-3	Figure 3 (injection gun 22 has a body 24 with removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20). Figure 6 (a generally cylindrical chamber or housing 72 adjacent heater 64 is provided to receive a cylindrical plug 74 of the thermoplastic material). Column 4, lines 51-53 (injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20). Column 6, lines 13-15 (a generally cylindrical chamber or housing 72 adjacent heater 64 is provided to receive a cylindrical plug 74 of the thermoplastic material).
4	Figure 7 (a piston for pressurizing the fluid). Column 6, lines 56-59 (a disk dilator assembly generally indicated at 100 having a cylindrical chamber 102 with an inert fluid such as saline therein and a piston 108 for pressurizing the fluid).
5-7	Figure 3 (a hand operated trigger for activating a force). Column 4, lines 59-62 (a hand operated trigger 42 may be activated for forcing thermoplastic material 20 from the end of needle 38 upon heating of the thermoplastic material 20 to a predetermined temperature).

Claim 20 has been amended as follows:

20. The injection device as defined in claim [4] 2, further comprising[;]:

a chamber for receiving a plug of said thermoplastic material; and

a hand operated trigger operatively connected to said plug thermoplastic material and upon actuation is effective to force said thermoplastic material from said needle when said thermoplastic material is heated to a flowing state.

Line No.	Support For Amendment
1-3	Figure 3 (injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20). Figure 6, (a generally cylindrical chamber or housing 72 adjacent heater 64 is provided to receive a cylindrical plug of the thermoplastic material 20). Column 4, line 51-53 (injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20). Column 6, lines 13-15 (a generally cylindrical chamber or housing 72 adjacent heater 64 is provided to receive a cylindrical plug 74 of the thermoplastic material).
4-6	Figure 3 (a hand operated trigger for activating a force). Column 4, lines 59-62 (a hand operated trigger 42 may be activated for forcing thermoplastic material 20 from the end of needl e38 upon heating of the thermoplastic material 20 to a predetermined temperature).

Claim 21 has been amended as follows:

21. The injection device as defined in claim [4] 20, [further comprising;] wherein:

[the] said chamber for receiving [the] said plug is provided in a plunger removable from an injection device body.

Line No.	Support For Amendment
4	Figure 3 & Column 4 lines 48-50 (injection of thermoplastic material 20 within the annulus fibrosus 12 by an injection device or gun illustrated schematically at 22 is shown. Injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20). Column 2, line 66 – Column 3, line 4 (The size of the needle may depend on such factors as the amount of thermoplastic material to be injected, the temperature of the thermoplastic being injected, and the axial pressure applied by the injection device, such as a piston or plunger, to the thermoplastic material to force the heated material from the end of the needle into the spine).

Claim 22 has been amended as follows:

22. The injection device [asa] as defined in claim [4] 2, further comprising[;]:

a heater control unit having an adjustable temperature control to provide a selected temperature for said [heater] heating element.

Line No.	Support For Amendment
1	Column 2, lines 61-67 (an injection device utilized for heating and injecting the thermoplastic material, the device may utilize a silver needle encased in ceramics).
3-4	Figure 3 and Column 4, lines 53-56 (a heater 28 is provided to heat the thermoplastic material 20 and a heater control unit 30 having an adjustable temperature control knob 32 is provided with a temperature readout at 34).

III. Claim Rejections – 35 USC § 103

All claims are currently allowed or have been amended to depend from allowed claims. Claims 1-11 are allowed. Claims 12-17, 19, 20, and 22 have been amended through this paper to depend from allowed claim 2. Claim 18 depends from claim 17, which depends from allowed claim 2. Claim 21 depends from claim 20, which depends from allowed claim 2. Claims 23 and 24 have been canceled. Based on the foregoing, discussion of the rejections is moot. Claims 12-22 are believed to be in condition for allowance, and a favorable indication in that regard is hereby earnestly solicited.

IV. Allowable Subject Matter

Applicants wish to thank the Examiner for the allowance of claims 1-11. As previously noted, all claims are currently allowed or have been amended to depend from allowed claims.

CONCLUSION

Reconsideration and allowance of the claims in this application is respectfully requested. It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment. In the event that there are any questions concerning this Response or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,
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